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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,670	07/23/2001	Andrew W. Taylor	ERI-114AX	6394
207	7590	02/10/2004	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

#### DETAILED ACTION

1. Applicant's election with traverse of Group V, Claim 24, filed 11/13/03, is acknowledged. Applicant argues that as all of claims in the application are directed to related aspects of the same general invention, search of all claims would pose no undue burden on the Examiner.

These arguments are not found persuasive for the following reasons. While the searches of the various methods of the instant claims may overlap, they are not coextensive. Particularly note that, because of the additional requirement of *in vivo* expression, methods of gene therapy, i.e., the elected invention, comprise numerous additional limitations and considerations, such as might include issues of dosage, concentration and delivery not associated with methods comprising treatment with a protein. Because a showing of noncoextensive searches has been accepted by the Office as a showing a serious search burden on the Examiner, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-23 and 25-41 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claim 24 is being acted upon.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,048,850 in view of Lipton et al. (1997, IDS).

The '850 patent teaches a method for down-regulating a T cell-mediated autoimmune response (arthritis) in a tissue site in an animal, comprising directly injecting genetic material for an anti-inflammatory compound, into or near the autoimmune-diseased tissue site (see particularly column 30, lines 48-64).

The reference teaching differs from the claimed invention only in that it does not teach the use of  $\alpha$ -MSH as the anti-inflammatory compound.

Lipton et al. teaches the use of  $\alpha$ -MSH as an anti-inflammatory compound for the down-regulation of a T cell-mediated autoimmune response (see particularly page 141, column 2, Box I).

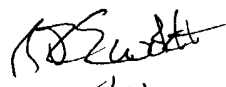
It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for down-regulating a T cell-mediated autoimmune response (arthritis) in a tissue site in an animal, comprising directly injecting genetic material for an anti-inflammatory compound, into or near the autoimmune-diseased tissue site, as taught by the '850 patent, employing  $\alpha$ -MSH as the anti-inflammatory compound, as taught by Lipton et al. One of ordinary skill in the art at the time the invention was made would have been motivated to employ  $\alpha$ -MSH as the anti-inflammatory compound of the invention because  $\alpha$ -MSH was a well-known anti-inflammatory compound at the time of the invention. It is well-established that the substituting of equivalents, in this instance one anti-inflammatory for another, for the same purpose is obvious, see MPEP 2144.06.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

**Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
2/5/04  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**